Advisory Panel on Healthcare Delivery and Disparities Research (HDDR) Supplementary Materials

I. Agenda

Advisory Panel on Healthcare Delivery and Disparities Research (HDDR)

May 6, 2021 (*Times listed in Eastern)* Webinar Link

11:00 AM	**Welcome, Introductions, and Setting the Stage** **Steve Clauser, PhD, MPA,** Director, HDDR, PCORI **Alicia Arbaje, PhD, MD, MPH** Associate Professor of Medicine and Director of Transitional Care Research, Johns Hopkins University, *HDDR Advisory Panel Co-Chair* **Jane Kogan, PhD,** Associate Chief Research and Translation Officer, UPMC Center for High-Value Health Care, *HDDR Advisory Panel Co-Chair*
11:20 AM	**HDDR Program Updates and Discussion** **Steve Clauser, PhD, MPA,** Director, HDDR, PCORI • Maternal Morbidity and Mortality: **Elisabeth Houtsmuller, PhD**, Associate Director, HDDR, PCORI • Intellectual and Developmental Disabilities: **Amanda Barbeau, MPH,** Senior Program Associate, CEDS, PCORI Discussion Facilitator: Jane Kogan
12:00 PM	**LUNCH BREAK**
12:30 PM	**PCORI COVID Activities** **William Lawrence, MD, MS,** Senior Clinical Advisor, Office of the CEDO, PCORI Discussion Facilitator: Alicia Arbaje
1:00 PM	**Leveraging Telehealth for Chronic Disease Management Among Vulnerable Populations with Complex Needs** **Carly Khan, PhD, MPH, RN,** Program Officer, HDDR, PCORI Discussion Facilitator: Jane Kogan
2:00 PM	**BREAK**
2:15 PM	**Strategic Planning: Identifying National Priorities for Health** **Steve Clauser, PhD, MPA,** Director, HDDR, PCORI Discussion Facilitator: Alicia Arbaje
3:00 PM	**Advancing Health Equity in a Comparative Effectiveness Research Framework** **Vivian Towe, PhD, Msc, MA,** Program Officer, HDDR, PCORI Discussion Facilitator: Alicia Arbaje & Jane Kogan
4:00 PM	**Wrap-Up and Next Steps** **Steve Clauser, PhD, MPA,** Director, HDDR, PCORI **Alicia Arbaje, PhD, MD, MPH** Associate Professor of Medicine and Director of Transitional Care Research, Johns Hopkins University, *HDDR Advisory Panel Co-Chair* **Jane Kogan, PhD** Associate Chief Research and Translation Officer, UPMC Center for High-Value Health Care, *HDDR Advisory Panel Co-Chair*
4:15 PM	**Adjourn**

II. New Award: Helping Patients Achieve Kidney Transplants through Health System Change

Cycle 1 2020: Improving Healthcare Systems

Principal Investigator: Leigh Ebony Boulware, MD, MPH, FACP

Institution: Duke University

Click here to see lay abstract on PCORI's website

Technical abstract
Background and Significance: Early kidney transplantation is an optimal treatment for kidney failure that significantly improves patients' length and quality of life. However, fewer than 5% of US patients initiate treatment with a kidney transplant. In response to the urgent need for improvement in early kidney transplant rates, the United States Department of Health and Human Services launched the 2019 Advancing American Kidney Health Initiative, a Presidential Executive Order which mandates that 80% of patients with kidney failure receive either a kidney transplant or dialysis at home by 2025. However, patients face numerous critical roadblocks on the path to obtaining early kidney transplants, including inadequate knowledge, difficulty discussing transplant with physicians and family, suboptimal transplant referral and evaluation rates, and failure to complete the transplant evaluation process. Patients need help to overcome these roadblocks, but comprehensive and effective strategies to overcome roadblocks have not been studied or implemented. Health systems have unique capabilities that could be leveraged to help patient and their families overcome these roadblocks and obtain early kidney transplants.

Study Aims: The team will study the effectiveness of a health system intervention to improve rates of early kidney transplantation. They will partner with patients, their families, and other stakeholders to (1) establish a 'Patient Centered Early Health System Transplant Outreach' program to overcome roadblocks patients and their families face in the process to achieve early kidney transplants; and (2) compare the effectiveness of Patient Centered Early Health System Transplant Outreach to the effectiveness of an intervention that will augment usual kidney care by alerting patients' physicians to clinical practice guidelines recommending early consideration of kidney transplants.

Study Description: This is a randomized comparative effectiveness trial in the Geisinger Health and Duke University Health systems. Geisinger is an integrated health system with an affiliated health plan serving a largely rural population in western Pennsylvania. Duke is a non-integrated academic health system serving a highly diverse (African Americans comprising nearly 45% of the nephrology clinic patients) which provides most patient care for Durham County, North Carolina—a mid-sized diverse metropolitan area in the Southeastern US. Both health systems provide nephrology care for patients and full-service transplant services. The study will recruit 800 adults who are eligible for early kidney transplants (age 18-75 years with estimated glomerular filtration rates of <30 ml/min/1.73m2 or increased risk of disease progression) to receive 'Patient Centered Early Health System Outreach' or usual kidney care augmented by alerts to physicians reminding them to initiate nephrology care and early discussions about kidney transplants. 'Patient Centered Early Health System Transplant Outreach' is a multi-component evidence-based intervention which will (1) identify patients qualifying for kidney transplants as early as possible, (2) support patients and their families with education and behavioral support to help them talk about and pursue early transplants, (3) proactively reach out to patients to let them know they are eligible for early transplants and invite them to the transplant center, and (4) navigate patients through the multi-step transplant evaluation process to completion using Freeman navigation skills. Usual kidney transplant care features guideline-based nephrology care, but it does not systematically identify patients for early transplants, proactively reach out to them, or navigate them through the transplant evaluation process to completion. The study's primary outcome will measure patients' pursuit of early kidney transplant at 6, 12, and 18 months after study initiation. This outcome will measure patients' behavioral activation and success with overcoming the critical roadblocks to early kidney transplants. The team will also measure health system records of patients' initiation and completion of kidney transplant evaluations, as well as patients' self-reported knowledge of kidney transplants and empowerment to overcome roadblocks. They will use general linear mixed models and time-to-event models to quantify differences in outcomes between comparator groups.

Significance and Potential Impact: This study will provide critically needed evidence to help guide health systems toward effective intentions to increase early kidney transplant rates and improve patients' lives.

Research Methods at a Glance:

Design Element	**Description**
Design	Randomized Clinical Trial
Population	Adults with chronic kidney disease
Interventions/Comparators	• Patient Centered Early Health System Outreach • Usual kidney care augmented with physician alerts
Outcomes	Patient Pursuit of Kidney Transplant
Timeframe	18 months

III. New Award: Utilizing PCORnet to Support Transition from Pediatric to Adult-Centered Care and Reduce Gaps in Recommended Care in Patients with Congenital Heart Disease

Cycle 2 2020: Conducting Rare Disease Research using PCORnet

Principal Investigator: Thomas Carton, PhD, MS

Institution: Louisiana Public Health Institute

Click here to see lay abstract on PCORI's website

Technical abstract
Background and Significance: Congenital heart defects (CHDs) are a heterogeneous group of rare diseases of varying severity, each diagnosis with its unique set of comorbidities. Guidelines for timely CHD related clinic visits and follow up testing exist for individual CHD subgroups; however, it is unclear how frequently these patients receive recommended care and what is the impact of that care on patient prioritized outcomes.

Study Aims: The study will develop an adult CHD surveillance program using PCORnet and robust stakeholder (patients, researchers and organizational) collaborations. Specifically, the team aims to obtain real-world estimates on healthcare use and comorbidities of various CHD subtypes, and determine the impact of gaps in recommended care on these outcomes (AIM 1); identify factors associated with higher or lower gaps in care (AIM 2); and evaluate the impact of gaps in care or differences in care on patient reported outcomes (PROs) such as quality of life, mental health, physical functioning and health service use. The long-term objectives of the study are to identify CHD subgroup specific care pathways that are more likely to improve outcomes that matter most to patients, and build evidence to conduct future comparative effectiveness research (CER) to facilitate implementation of effective management approaches.

Study Description: The study team has planned an observational cohort study that will compare the outcomes of healthcare use, comorbidities and PROs among CHD patients with and without gaps in care (defined as no cardiology follow-up for >2 years for complex and >3 years for noncomplex CHD subgroup). For aims 1 and 2, they will identify CHD patients using the International Classification of Diseases (ICD)-9 or 10 codes from a total of 14 PCORnet sites over a 7-year period. They anticipate identifying ~74000 subjects (~51000 non-complex; 23000 complex CHD) > 18 years of age who have about 6 years of data available before they turned 18 and a year data on follow-up. They will collect information about patient- (age, gender, race/ethnicity, socioeconomic status) and hospital variables (availability of CHD providers, teaching vs. nonteaching hospital, rural vs urban). The outcome variables will include rates of healthcare use (outpatient, emergency department, inpatient use) and comorbidities (cardiac and noncardiac) for Aim 1; and rates of gaps in care for Aim 2. Unadjusted and adjusted regression analysis will be used to determine the association of gaps in care with outcomes (Aim 1) and factors associated with gaps in care (Aim 2). Each PCORI site will help in recruitment of the patients identified in Aims 1 and 2 into the Congenital Heart Initiative (CHI) registry, the first Adult CHD patient-powered registry, to determine the association of gaps in care with PROs (Aim 3). The team anticipates enrollment of ~280 patients/ month (20 patients/site/month x 14 sites) who will then be engaged to complete pre-validated questionnaires evaluating PROs, reasons for gaps in care and their reported healthcare use. Descriptive and regression analysis as appropriate will be performed to determine the association of gaps in care (predictor) with PROs (outcome measures) for Aim 3. In all Aims, CHD subgroup specific analysis will be performed. Data extraction from PCORnet sites will occur during month 9 and 31 of the study period and data from CHI Registry on PROs, reasons for gaps in care and healthcare use will be collected during months 10 to 21.

Significance and Potential Impact: The findings of this study will provide valuable information to CHD patients, clinicians/ researchers and healthcare organizations/ payors. The data from this study could provide healthcare organizations with the evidence to support the CHD clinicians with the infrastructure and resources to develop and implement care pathways that could be effective in improving the outcomes that matter most to the patients, and thus will facilitate adherence to recommended care and higher quality of care. This study has tremendous potential to advance research regarding CHD specific lesions using PCORnet by leveraging the robust collaborations from numerous key stakeholders including ACHA, a national patient advocacy organization dedicated to the health of adult CHD patients, and scientific collaborators AARCC, a North American network of over 50 CHD researchers. By utilizing the strength of PCORnet, they will answer a set of stakeholder prioritized research questions and will establish a PCORnet-based infrastructure to conduct CER on CHD patients in the future.

Research Methods at a Glance:

Design Element	**Description**
Design	Prospective Cohort Design
Population	Adults aged 18 and older with CHD (as identified by ICD9/ICD10 codes)
Interventions/Comparators	This study will use PCORnet to examine the effects of gaps in recommended care (cardiology visits) on patient-prioritized outcomes for adults with noncomplex and complex subtypes of CHD.
Outcomes	Primary: Healthcare utilization and comorbidities Secondary: Predictors of loss to follow-up and patient-reported outcomes
Timeframe	3 years

IV. New Award: Advancing Perinatal Mental Health and Wellbeing: The DC Mother-Infant Behavioral Wellness Program

Cycle 1 2020: Addressing Disparities

Principal Investigator: Catherine Limperopoulos, PhD

Institution: Children's Research Institute

Click here to see lay abstract on PCORI's website

Technical abstract

Background and Significance: Mental health (MH) disorders, including stress, anxiety, and depression, are the most common complication of pregnancy, with enormous racial disparities in prevalence and care. The prevalence of these disorders is almost two-fold higher among pregnant low-income African American (AA) women who, paradoxically, also face the greatest obstacles to MH care. These racial disparities are particularly striking in the District of Columbia (DC) and have been exacerbated by the worsening COVID-19 pandemic. Numerous local and national agencies, expert opinion guidelines and patient-centered "think tanks" have highlighted the enormous public health impact of this problem, which has potentially serious consequences for the mother, the pregnancy, the offspring across the lifespan, and possibly into the next generation. Mental health disorders remain seriously under-detected in part due to poor implementation of recommended screening protocols. In addition, engaging and retaining affected AA women in MH care is complicated by significant psychosocial stressors, cultural barriers, stigma, and distrust. In this proposal, we plan to partner with stakeholders from within low-income AA communities to develop and implement strategies that reduce these obstacles to screening and provide appropriate evidence-based, culturally relevant interventions during this critical period spanning from pregnancy to the first year postpartum.

Study Aims: The study team's overarching objective is to develop and evaluate a collaborative, multi-dimensional and culturally tailored community-based model of integrated perinatal MH care. The target population is low-income AA women with pregnancy-related stress, anxiety, and depression. The study will address the following stakeholder-driven specific aims: (1) refine an individualized plan to integrate patient navigation and a culturally adapted cognitive-behavioral (CBT) intervention for low-income AA pregnant women designed to increase recruitment and retention within the healthcare community system, and (2) through a two-arm prospective randomized controlled design, women who are subthreshold and threshold risk for prenatal stress, depression and/or anxiety will participate in one of two interventions: (a) existing prenatal intervention (usual care); or (b) patient navigation plus culturally adapted CBT, and peer support groups.

Study Description: The team will screen 1,000 low-income pregnant AA women (18-45 years of age) in their second pregnancy visit with validated tools for stress, anxiety, and depression. They expect to identify 700 study participants who will enter the intervention arm and randomize to the two conditions above (n=350/condition). Additionally, women will participate in a clinical interview to be divided in two subgroups: (1) subthreshold (do not meet criteria for major depression or anxiety), or (2) threshold (meet DSM-5 criteria for depression and/or anxiety). The subthreshold and threshold subgroups will receive culturally adapted CBT in group and individual modality, respectively. Both subgroups also have the option to participate in virtual peer support groups. Participants will complete standardized health (including mental health) and well-being questionnaires during pregnancy at their prenatal site, and up to 12 months after delivery at their well-baby visits, when they also will complete questionnaires about their infants' development and behavior. All infants also will undergo a standardized developmental test at 12 months. Health care utilization and outcomes also will be collected through electronic medical records.

Significance and Potential Impact: Patient/family-centered outcomes will include rates and levels of maternal stress, anxiety, and depression; risk and protective factors; maternal outcomes; intervention engagement and adherence; health experiences and health care utilization; and infant outcomes, including neonatal health and behavior-developmental outcomes; and attachment. The diverse team will include patient and community stakeholders, obstetricians, midwives, pediatricians, perinatal and child psychologists, national content experts, and policy advisers with expertise in care delivery system operations, payment policy and operations, and developing IT solutions and scaling up reach from the local to the national level.

Research Methods at a Glance:

Design Element	**Description**
Design	Prospective randomized controlled clinical trials
Population	African American women aged 18-45 with moderate or severe stress, anxiety or depression
Interventions/Comparators	• Usual prenatal care • Patient navigator and adapted CBT and peer support group
Outcomes	Rates and levels of maternal stress, anxiety, and depression; risk and protective factors; maternal outcomes; intervention engagement and adherence; health experiences and healthcare utilization; and infant outcomes, including neonatal health and behavior-developmental outcomes; and attachment
Timeframe	36 months

V. Upcoming PCORI Public Events

Advisory Panel on Rare Disease Spring 2021 Meeting

Friday, May 14, 2021 1:00PM-5:00PM EDT

Register Here

Board of Governors Meeting

Monday, May 24, 2021 9:00AM EDT – Tuesday, May 25, 2021 5:00PM EDT

More Details Here. Registration Coming Soon.

Advisory Panel on Patient Engagement Summer 2021 Meeting

Thursday, July 15, 2021 11:30AM EDT – Friday, July 16, 2021 3:30PM EDT

Register Here

2021 PCORI Virtual Annual Meeting

Wednesday, November 17, 2021 9:00AM EST – Friday, November 19, 2021 5:00PM EST

More Details Here. Registration Coming Soon.